

REMARKS/ARGUMENTS

Applicants have studied the Office Action dated October 19, 2007, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance.

Claims 1 to 10, 17, 18, and 21 to 32 remain in the application. Claims 1, 17, 21, 22, and 32 have been amended. Claims 11 to 16 and 19 to 20 were canceled in a previous amendment to facilitate prosecution of the instant application. Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

In the Office Action, the Examiner:

- (1) responded to applicant's withdrawal of the appeal and the reopening of the prosecution;
- (2) acknowledged the filing of an information disclosure statement (IDS);
- (3) rejected claims 1 to 4, 7, 17, 18, 21 to 25, 28 and 32 under 35 U.S.C. § 102(b) as being anticipated by Nakao et al. (U.S. 5,222,961; hereinafter "Nakao").
- (4-6) rejected claims 5, 6, 8 to 10, 26, 27, and 29 to 31 under 35 U.S.C. § 103(a) as being unpatentable over Nakao and in further view of Barrows et al. (U.S. 4,719,917; hereinafter "Barrows") and as evidenced by Oberlander (U.S. 5,002,562).

Rejection under 35 U.S.C. §102(b) Nakao

The Examiner rejected claims 1 to 4, 7, 17, 18, 21 to 25, 28, and 32 under 35 U.S.C. § 102(b) as being anticipated by Nakao (U.S. Pat. No. 5,222,961). These claims have been amended to overcome the cited prior art.

Now, claims 1, 17, 21, 22, and 32 recite, *inter alia*:

a first arm;
a second arm substantially parallel to said first arm; and
a bridge connecting said first and second arms to form a substantially static U-shaped structure.

As set forth in the instant application, the surgical clip is inserted by the clip applicator after the clip applicator jaws grasp and puncture the invaginated fundus. The tissue is plicated and the retainer and arms are caused to slide over the tissue for a distance. Then, *only* the retainer portion of the surgical clip is plastically deformed to affix the clip to the fundus (shown in Fig 13 below).

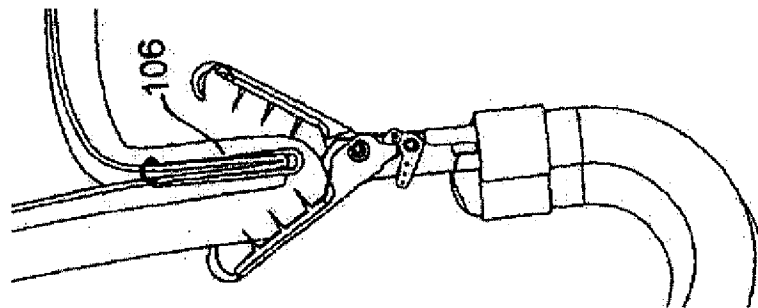


Figure 13

As viewed, for example, in FIGS. 17 to 20 (which are reproduced below for the Examiner's convenience), the surgical clip of claim 1 has an initial state where the bridge connects a first arm to a substantially **parallel** second arm in a substantially **static** U-shaped structure.

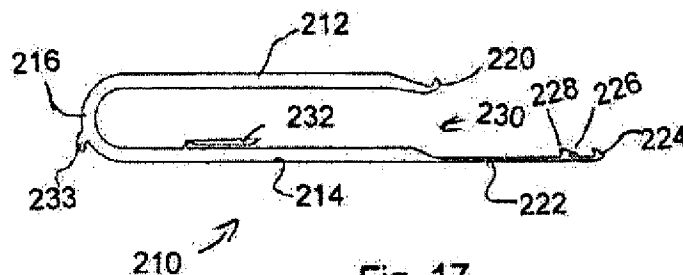


Fig. 17

The claimed surgical clip maintains this static U-shaped structure when exiting the jaws of the end effector and while the retainer is penetrating the tissue (for example, of the

fundus). As stated in the Detailed Description (col. 9, lines 11-16), the first and second arms, as well as the bridge portion of the claimed clip are relatively stiff and are not plastically deformable within the limits of force applied to the arms during use. Only the retainer section of the clip (e.g., 222, 320, 322, 420, and 422) is relatively easily plastically deformable by the clip applicator. *Id.* This means that the bridge and arms form a “substantially static U-shaped structure”, as set forth in the claims.

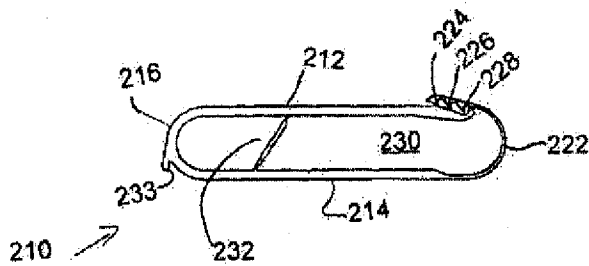
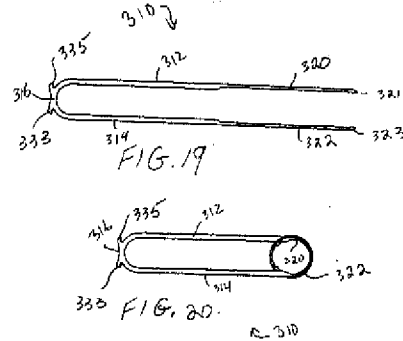


Fig. 18

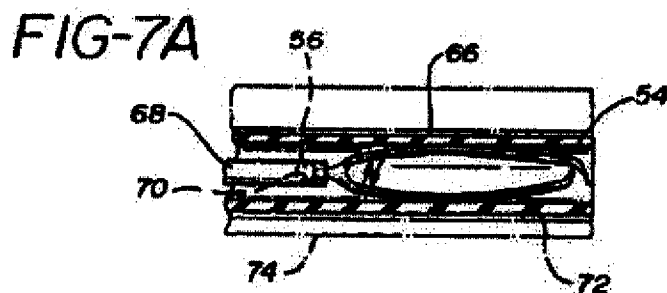


The second arm being substantially parallel to the first arm and the substantially static U-shaped structure of the bridge and arms are two features that are not present in or suggested by Nakao.

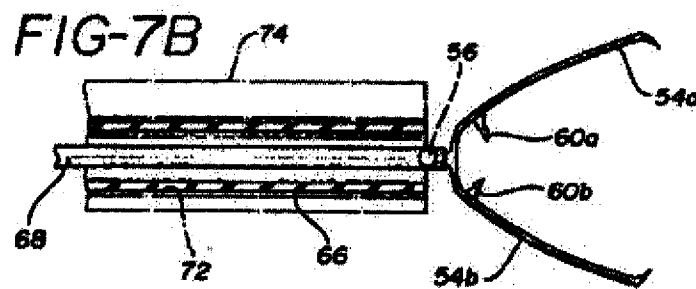
The Examiner argues that the Nakao staple is capable of being deformed because Nakao teaches that the staple is made of a flexible material (col. 9, lines 41-44). This being accepted as true, then, by definition, the Nakao staple cannot have a “substantially static U-shaped structure.”

The Examiner has argued that the Nakao staple has a first and second arm connected through a bridge to form a substantially U-shaped structure. The claims of the present application require that the first and second arms be “substantially parallel.” After a thorough examination of the Nakao disclosure, the Nakao staple cannot be said to have “substantially parallel” arms. As shown in Nakao’s FIG. 7A (reproduced below), the

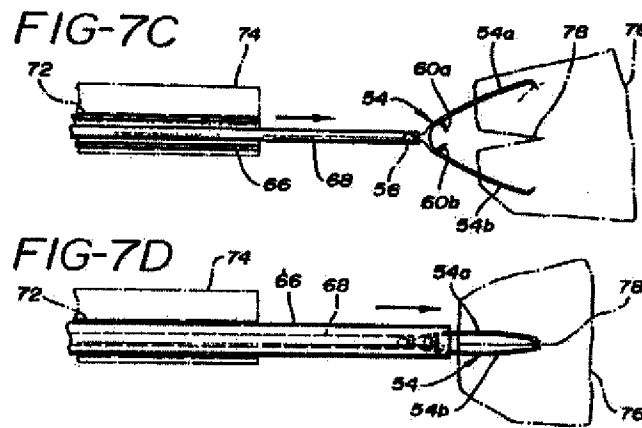
Nakao staple is compressed pre-installation and, in this state, the arms cannot be considered parallel *because they are curved along their entire extent*.



Even if one were to find that these arms were "parallel" (a conclusion to which applicants cannot agree), during the insertion operation, the arms of the Nakao staple deviate from the position of FIG. 7A -- due to the built-in outward spring bias -- to place the arms in an open position pictured in Nakao FIG. 7B (below; see *also* Nakao at col. 9, lines 39-41).



The Nakao staple returns to the position of FIG. 7A *only* when a tubular member counteracts the outward-biased spring forces of the staple. This externally induced movement causes the barbs or hooks 60a,b of the finger elements to interlock and hold the staple legs in a closed configuration shown below in Nakao's FIGS. 7C and 7D (see *also* Nakao at col. 10, lines 4-12).



This structure is distinctively different from the surgical clip of the present invention because the clip, *as claimed*, does not deviate from its “substantially parallel” arms and its “substantially static U-shaped” position during the entire insertion process. The only part of the claimed invention that plastically deforms is the retainer. See, e.g., FIG. 13 (above).

Other features of the surgical clip of the independent claims (1, 17, 21, and 32) include:

- at least one deformable retainer extending from one end of the arms in a direction; and
- the retainer having a length in that direction of at least approximately π or 2.5 times the distance between the arms when the arms are substantially parallel.

The Nakao clip cannot be said to suggest these features, let alone disclose them as required by Section 102.

The retainer portion of the claimed surgical clip is designed to be deformable and the arms and bridge are substantially not deformable. The retainer has a specified length of π times the distance between the arms “when the arms are substantially parallel.” (Emphasis added.) When the claimed clip is inserted through the jaws, only the retainer (not the arms or the bridge) is designed to plastically deform and pierce tissue. See, e.g., FIGS. 13 and 25. The claimed length of the retainer allows for sufficient

penetration into the tissue so that it can move towards the other arm, either to connect thereto in a lock (see FIG. 18) or to curve in a circle (see FIG. 20).

Nakao does not have the retainer as prescribed in the claims of the instant application. To the contrary, the Nakao staple moves at a hinge joint. Once the arms are inserted into the tissue, they are then moved together. Finally, the hooks 60a,b present on the inside surface of the arms lock the staple arms in place. With such a configuration, the portion of the Nakao staple *that penetrates inside the tissue does not deform* (see FIGS. 7C and 7D), unlike the retainers of the claimed surgical clip. Because it is the arms of the Nakao staple that enter the tissue, the Nakao staple cannot be said to have a retainer extending from arms as set forth in the instant claims.

Even if the portion of the Nakao staple inserted into the tissue is referred to as a “retainer” (a conclusion to which applicants cannot agree), then the Nakao staple would not have the required parallel arms of the instant claims. More specifically, if the portion of the staple *inside the tissue* shown in FIGS. 7C and 7D is defined as a “retainer”, then the Nakao staple is deficient for anticipating the claims of the instant invention for two reasons. First, the remainder of the staple outside the tissue would have to include two parallel arms and these arms would have to be attached to a bridge to form a static U-shaped structure. What is left of the Nakao staple outside the tissue is merely a hinge structure. As shown in the drawings, this hinge cannot be a static u-shaped structure because it would no longer be a “hinge.” Second, the “arms” defined by the portion of the staple outside the tissue, are not parallel in any way. They are curved along their entirety and, by definition, cannot be considered parallel as set forth in the instant claims.

Because the elements in independent claims 1, 17, 21, 22, and 32 of the instant application are neither taught nor disclosed by Nakao, the clip of Nakao cannot anticipate the present invention. The dependent claims are believed to be patentable as well because they all are ultimately dependent on these independent claims. The Applicants respectfully submit that the Examiner’s rejection under 35 U.S.C. § 102(b) has been overcome.

Rejection under 35 U.S.C. §103(a) Nakao in view of Barrows and Oberlander

The Examiner rejected claims 5, 6, 8-10, 26, 27, and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over Nakao and in further view of Barrows et al. (U.S. 4,719,917; hereinafter "Barrows") and as evidenced by Oberlander (U.S. 5,002,562).

As set forth above, each of the independent claims is believed to be allowable.

Because each of the rejected claims is dependent upon one of the allowable independent claims 1, 17, 21, 22, or 32, these dependent claims are allowable due to their dependency.

CONCLUSION

The remaining cited references have been reviewed and are not believed to affect the patentability of the claims as amended.

In this Response, Applicant has amended certain claims. In light of the Office Action, Applicant believes these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

Applicant acknowledges the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record. The foreseeable equivalents of any territory surrendered by amendment are limited to the territory taught by the information of record. No other territory afforded by the doctrine of equivalents is knowingly surrendered and everything else is unforeseeable at the time of this amendment by the Applicants and their attorneys.

Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in

condition for allowance, which allowance is respectfully requested.

If an extension of time for this paper is required, petition for extension is herewith made.

It is believed that no fee is due with this Amendment. However, if any fees are due with respect to Sections 1.16 or 1.17, please charge to the deposit account of the undersigned firm, Acct. No. 503,836.

PLEASE CALL the undersigned if that would expedite the prosecution of this application.

Respectfully submitted,

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